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Case 7804

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of :
Douglas J. Dobrozsi et al. :
Continuation Prosecution Application :
Serial No.: 09/467,333 : Group Art Unit: 1617
Filed: December 20, 1999 : Examiner: H. Nguyen
Title: Compositions Having Improved Stability:

PRELIMINARY AMENDMENT UNDER 37 CFR 1.115

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Please preliminarily amend the above-identified continuation prosecution application as follows and consider the accompanying remarks.

IN THE SPECIFICATION:

At page 8, please delete the paragraph at lines 13-28 and insert therefor

-- Reducing agents are substances that have a lower redox potential than the drug or adjuvant that they are intended to protect against oxidation. Thus reducing agents are more readily oxidized than the drug or adjuvant and are effective in the presence of oxidizing agents. See W. Lund The Pharmaceutical CODEX, 12th Edition, p.290, The Pharmaceutical Press, 1994, incorporated herein by reference. Reducing agents of the present invention have an electrode potential value. This is defined by the Nernst equation and practically measured using standard electrochemical reference cells. The resulting values are therefore called the Standard Electrode Potential, of E^0 as measured in volts of (V). Comparing standard electrode potentials for different substances can be used to assess the effectiveness of different reducing agents; see Wells, Pharmaceutical Preformulation, Ellis Horwood Limited Publishing, 1988, pp. 168-172; incorporated herein by reference. The reducing agents useful in the present invention have an Electrode Potential value E^0 greater than about -0.119V, preferably from about -0.119V to +0.250V. Preferred reducing agents are selected from the group consisting of the salts of meta bisulfite and bisulfite, including their sodium and potassium salts, dithiothreitol, thiourea, sodium thiosulphate, thioglycolic acid, tert-butyl hydroquinone (TBHQ), acetyl cysteine, hydroquinone, and mixtures thereof.--

IN THE ABSTRACT:

Please replace the present Abstract with the one submitted herewith on a separate page.